BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	)	
BEIRU JIA CHEN, M.D.	)	**Case No. 8002013000122**
Physician's and Surgeon's Certificate No. C51848	)	
Respondent	)	

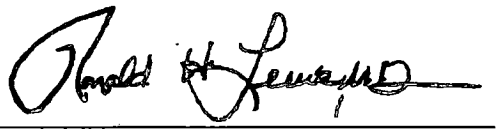
DECISION

The attached Stipulated Settlement and Disciplinary Order is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on December 8, 2017.

IT IS SO ORDERED: November 8, 2017.

MEDICAL BOARD OF CALIFORNIA



Ronald H. Lewis, M.D., Chair
Panel A

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BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **BEIRU JIA CHEN, M.D.** **6965 El Camino Real, Suite 105-618** **Carlsbad, CA 92009** **Physician's and Surgeon's Certificate No. C 51848,** Respondent.	Case No. 800-2013-000122 OAH No. 2017010807 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Kimberly Kirchmeyer (Complainant) is the Executive Director of the Medical Board of California (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Beneth A. Browne, Deputy Attorney General.

2. BEIRU JIA CHEN, M.D. (Respondent) is represented in this proceeding by attorney Tracy Green, Esq., whose address is: Tracy Green, Esq., Green & Associates, 800 West 6th Street, Suite 450, Los Angeles, CA 90017.

3. On or about January 14, 2005, the Board issued Physician's and Surgeon's Certificate No. C 51848 to Respondent. The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought in Accusation No. 800-2013-000122, and will expire on October 31, 2018, unless renewed.

JURISDICTION

4. Accusation No. 800-2013-000122 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 7, 2016. Respondent timely filed her Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 800-2013-000122 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 800-2013-000122. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against her; the right to present evidence and to testify on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 800-2013-000122, if proven at a hearing, constitute cause for imposing discipline upon her Physician's and Surgeon's Certificate.

10. Respondent does not contest that, at an administrative hearing, complainant could establish a *prima facie* case with respect to the charges and allegations contained in Accusation No. 800-2013-000122 (with a modification at page 3, line 21, correcting the year 2016, to instead state 2013), and that Respondent hereby gives up her right to contest those charges.

11. Respondent agrees that if she ever petitions for early termination or modification of probation, or if the Board ever petitions for revocation of probation, all of the charges and allegations contained in Accusation No. 800-2013-000122 (with a modification at page 3, line 21, correcting the year 2016, to instead state 2013) shall be deemed true, correct and fully admitted by respondent for purposes of that proceeding or any other licensing proceeding involving respondent in the State of California.

12. Respondent agrees that her Physician's and Surgeon's Certificate is subject to discipline and she agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CIRCUMSTANCES IN MITIGATION

13. Respondent has never been the subject of any disciplinary action. She is admitting responsibility at an early stage in the proceedings.

CONTINGENCY

14. This stipulation shall be subject to approval by the Medical Board of California. Respondent understands and agrees that counsel for Complainant and the staff of the Medical Board of California may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or her counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw her agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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15. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Physician's and Surgeon's Certificate No. C 51848 issued to Respondent is revoked. However, the revocation is stayed and Respondent is placed on probation for four (4) years on the following terms and conditions.

1. EDUCATION COURSE. Within 60 calendar days of the effective date of this Decision, and on an annual basis thereafter, Respondent shall submit to the Board or its designee for its prior approval educational program(s) or course(s) which shall not be less than 40 hours per year, for each year of probation. The educational program(s) or course(s) shall be aimed at correcting any areas of deficient practice or knowledge and shall be Category I certified. The educational program(s) or course(s) shall be at Respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure. Following the completion of each course, the Board or its designee may administer an examination to test Respondent's knowledge of the course. Respondent shall provide proof of attendance for 65 hours of CME of which 40 hours were in satisfaction of this condition.

2. MEDICAL RECORD KEEPING COURSE. Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in a course in medical record keeping approved in advance by the Board or its designee. Respondent shall provide the approved course provider with any information and documents that the approved course provider may deem pertinent. Respondent shall participate in and successfully complete the classroom component of the course not later than six (6) months after Respondent's initial enrollment. Respondent shall successfully complete any other component of the course within one (1) year of enrollment. The medical record keeping course shall be at Respondent's expense and shall be in addition to the Continuing

Medical Education (CME) requirements for renewal of licensure.

A medical record keeping course taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the course would have been approved by the Board or its designee had the course been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the course, or not later than 15 calendar days after the effective date of the Decision, whichever is later.

3. CLINICAL COMPETENCE ASSESSMENT PROGRAM. Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in a clinical competence assessment program approved in advance by the Board or its designee. Respondent shall successfully complete the program not later than six (6) months after Respondent's initial enrollment unless the Board or its designee agrees in writing to an extension of that time.

The program shall consist of a comprehensive assessment of Respondent's physical and mental health and the six general domains of clinical competence as defined by the Accreditation Council on Graduate Medical Education and American Board of Medical Specialties pertaining to Respondent's current or intended area of practice. The program shall take into account data obtained from the pre-assessment, self-report forms and interview, and the Decision(s), Accusation(s), and any other information that the Board or its designee deems relevant. The program shall require Respondent's on-site participation for a minimum of three (3) and no more than five (5) days as determined by the program for the assessment and clinical education evaluation. Respondent shall pay all expenses associated with the clinical competence assessment program.

At the end of the evaluation, the program will submit a report to the Board or its designee which unequivocally states whether the Respondent has demonstrated the ability to practice safely and independently. Based on Respondent's performance on the clinical competence assessment, the program will advise the Board or its designee of its recommendation(s) for the

scope and length of any additional educational or clinical training, evaluation or treatment for any medical condition or psychological condition, or anything else affecting Respondent's practice of medicine. Respondent shall comply with the program's recommendations.

Determination as to whether Respondent successfully completed the clinical competence assessment program is solely within the program's jurisdiction.

If Respondent fails to enroll, participate in, or successfully complete the clinical competence assessment program within the designated time period, Respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. The Respondent shall not resume the practice of medicine until enrollment or participation in the outstanding portions of the clinical competence assessment program have been completed. If the Respondent did not successfully complete the clinical competence assessment program, the Respondent shall not resume the practice of medicine until a final decision has been rendered on the accusation and/or a petition to revoke probation. The cessation of practice shall not apply to the reduction of the probationary time period.

Within 60 days after Respondent has successfully completed the clinical competence assessment program, Respondent shall participate in a professional enhancement program approved in advance by the Board or its designee, which shall include quarterly chart review, semi-annual practice assessment, and semi-annual review of professional growth and education. Respondent shall participate in the professional enhancement program at Respondent's expense during the term of probation, or until the Board or its designee determines that further participation is no longer necessary.

4. NOTIFICATION. Within seven (7) days of the effective date of this Decision, the Respondent shall provide a true copy of this Decision and Accusation to the Chief of Staff or the Chief Executive Officer at every hospital where privileges or membership are extended to Respondent, at any other facility where Respondent engages in the practice of medicine, including all physician and locum tenens registries or other similar agencies, and to the Chief Executive Officer at every insurance carrier which extends malpractice insurance coverage to Respondent. Respondent shall submit proof of compliance to the Board or its designee within 15

calendar days.

This condition shall apply to any change(s) in hospitals, other facilities or insurance carrier.

5. SUPERVISION OF PHYSICIAN ASSISTANTS AND ADVANCED PRACTICE NURSES. During probation, Respondent is prohibited from supervising physician assistants and advanced practice nurses.

6. OBEY ALL LAWS. Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California and remain in full compliance with any court ordered criminal probation, payments, and other orders.

7. QUARTERLY DECLARATIONS. Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Board, stating whether there has been compliance with all the conditions of probation.

Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

8. GENERAL PROBATION REQUIREMENTS.

Compliance with Probation Unit

Respondent shall comply with the Board's probation unit.

Address Changes

Respondent shall, at all times, keep the Board informed of Respondent's business and residence addresses, email address (if available), and telephone number. Changes of such addresses shall be immediately communicated in writing to the Board or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021(b).

Place of Practice

Respondent shall not engage in the practice of medicine in Respondent's or patient's place of residence, unless the patient resides in a skilled nursing facility or other similar licensed facility.

License Renewal

Respondent shall maintain a current and renewed California physician's and surgeon's

license.

Travel or Residence Outside California

Respondent shall immediately inform the Board or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than thirty (30) calendar days.

In the event Respondent should leave the State of California to reside or to practice, Respondent shall notify the Board or its designee in writing 30 calendar days prior to the dates of departure and return.

9. INTERVIEW WITH THE BOARD OR ITS DESIGNEE. Respondent shall be available in person upon request for interviews either at Respondent's place of business or at the probation unit office, with or without prior notice throughout the term of probation.

10. NON-PRACTICE WHILE ON PROBATION. Respondent shall notify the Board or its designee in writing within 15 calendar days of any periods of non-practice lasting more than 30 calendar days and within 15 calendar days of Respondent's return to practice. Non-practice is defined as any period of time Respondent is not practicing medicine as defined in Business and Professions Code sections 2051 and 2052 for at least 40 hours in a calendar month in direct patient care, clinical activity or teaching, or other activity as approved by the Board. If Respondent resides in California and is considered to be in non-practice, Respondent shall comply with all terms and conditions of probation. All time spent in an intensive training program which has been approved by the Board or its designee shall not be considered non-practice and does not relieve Respondent from complying with all the terms and conditions of probation. Practicing medicine in another state of the United States or Federal jurisdiction while on probation with the medical licensing authority of that state or jurisdiction shall not be considered non-practice. A Board-ordered suspension of practice shall not be considered as a period of non-practice.

In the event Respondent's period of non-practice while on probation exceeds 18 calendar months, Respondent shall successfully complete the Federation of State Medical Boards' Special Purpose Examination, or, at the Board's discretion, a clinical competence assessment program.

that meets the criteria of Condition 18 of the current version of the Board's "Manual of Model Disciplinary Orders and Disciplinary Guidelines" prior to resuming the practice of medicine.

Respondent's period of non-practice while on probation shall not exceed two (2) years.

Periods of non-practice will not apply to the reduction of the probationary term.

Periods of non-practice for a Respondent residing outside of California will relieve Respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey All Laws; General Probation Requirements; Quarterly Declarations; Abstain from the Use of Alcohol and/or Controlled Substances; and Biological Fluid Testing.

11. COMPLETION OF PROBATION. Respondent shall comply with all financial obligations (e.g., restitution, probation costs) not later than 120 calendar days prior to the completion of probation. Upon successful completion of probation, Respondent's certificate shall be fully restored.

12. VIOLATION OF PROBATION. Failure to fully comply with any term or condition of probation is a violation of probation. If Respondent violates probation in any respect, the Board, after giving Respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

13. LICENSE SURRENDER. Following the effective date of this Decision, if Respondent ceases practicing due to retirement or health reasons or is otherwise unable to satisfy the terms and conditions of probation, Respondent may request to surrender his or her license. The Board reserves the right to evaluate Respondent's request and to exercise its discretion in determining whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, Respondent shall within 15 calendar days deliver Respondent's wallet and wall certificate to the Board or its designee and Respondent shall no longer practice medicine. Respondent will no longer be subject

to the terms and conditions of probation. If Respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

14. PROBATION MONITORING COSTS. Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Board, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Board or its designee no later than January 31 of each calendar year.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tracy Green, Esq. I understand the stipulation and the effect it will have on my Physician's and Surgeon's Certificate. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Medical Board of California.

DATED: 18 Aug 2017

BEIRU JIA CHEN, M.D.
Respondent

I have read and fully discussed with Respondent BEIRU JIA CHEN, M.D. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 8/18/17

TRACY GREEN, ESQ.
Attorney for Respondent

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Medical Board of California.

Dated: August 18, 2017

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
E. A. JONES III
Supervising Deputy Attorney General

Beneth A Browne

BENETH A. BROWNE
Deputy Attorney General
Attorneys for Complainant

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EXHIBIT A

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BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Investigation Against: **BEIRU JIA CHEN, M.D.** **6965 El Camino Real, Suite 105-618** **Carlsbad, CA 92009-4100** **Physician's and Surgeon's Certificate No. C51848,** Respondent.	Case No. 800-2013-000122 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Kimberly Kirchmeyer (Complainant) brings this Accusation solely in her official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On or about January 14, 2005, the Medical Board issued Physician's and Surgeon's Certificate Number 51848 to Beiru Jia Chen, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2016, unless renewed.

JURISDICTION

3. This Accusation is brought before the Board, under the authority of the following

laws. All section references are to the Business and Professions Code unless otherwise indicated.

4. Section 2229 of the Code states, in subdivision (a):

"Protection of the public shall be the highest priority for the Division of Medical Quality,[1] the California Board of Podiatric Medicine, and administrative law judges of the Medical Quality Hearing Panel in exercising their disciplinary authority."

5. Section 2227 of the Code provides that a licensee who is found guilty under the Medical Practice Act may have his or her license revoked, suspended for a period not to exceed one year, placed on probation and required to pay the costs of probation monitoring, or such other action taken in relation to discipline as the Board deems proper.

6. Section 2234 of the Code, states:

"The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

"(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.

"(b) Gross negligence.

"(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

"(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

"(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

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[1] Pursuant to section 2002 of the Business and Professions Code, the term "Division of Medical Quality" as used in the Medical Practice Act is deemed to refer to the Board.

"(d) Incompetence.

"(e) The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon.

"(f) Any action or conduct which would have warranted the denial of a certificate.

"(g) The practice of medicine from this state into another state or country without meeting the legal requirements of that state or country for the practice of medicine. Section 2314 shall not apply to this subdivision. This subdivision shall become operative upon the implementation of the proposed registration program described in Section 2052.5.

"(h) The repeated failure by a certificate holder, in the absence of good cause, to attend and participate in an interview by the board. This subdivision shall only apply to a certificate holder who is the subject of an investigation by the board."

7. Section 2266 of the Code states: "The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct."

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

8. Respondent is subject to disciplinary action under section 2234, subdivision (b), in that she was grossly negligent in handling the pathology cases of 4 patients. The circumstances are as follows:

Patient J.D.

9. On or about February 6, 2016, pelvic washings of patient J.D. were submitted to the Kern Medical Center (KMC) lab where Respondent worked as a pathologist. Patient J.D.'s pre-op diagnosis had been pelvic mass and rule out neoplasm. Respondent evaluated the cytology case. She ordered a calretinin immunostain from a separate lab for her interpretation.[2] She failed to order any other immunostains.

[2] The calretinin immunostain is a commonly used marker for mesothelial cells (benign or malignant) in the context of body cavity fluid cytology with abnormal cells of uncertain type.

10. On or about February 14, 2013, Respondent signed out the cytology case. Her pathology report documented "chronic inflammatory and reactive mesothelial cells, which stain positive for calretinin. No evidence of malignancy." In fact, independent of any consideration of which immunostains or other stains may have been indicated, the sample was overtly malignant. The features, particularly in the cell block, were clearly malignant and were highly suggestive of adenocarcinoma.

11. On or about October 30, 2013, the case was sent to another lab where additional immunostains were performed, targeting adenocarcinoma and repeating the calretinin stain as had been performed earlier. Although there were many mesothelial cells,[3] the calretinin immunostain showed that the limited malignant cells as shown were completely negative for calretinin. Adenocarcinoma was shown.

12. Taken individually or collectively, Respondent committed gross negligence when she:

(a) Failed to recognize malignancy of any type before ordering stains;

(b) Failed to diagnose or classify the malignancy;

(c) Failed to order a multi-stain panel; and

(d) Misinterpreted the calretinin stain as being positive for calretinin.

Patient J.H.

13. On or about October 9, 2012, patient J.H., a 52-year-old female underwent a CT-guided biopsy. Documentation initially reflected CT-guided biopsy of "mediastinum" but Respondent added the word "lung." A note in patient J.H.'s medical record signed on October 7, 2012, described a mass encasing the pulmonary artery and also that the patient had a major smoking history.

14. At the time of the procedure, Respondent examined two air dried smears. Respondent communicated that the smears were "adequate for interpretation" and Respondent did

[3] Many mesothelial cells would be expected because there are always benign mesothelial cells in body cavity washings, even when other malignant cells are also present.

not request any additional sample.[4] The procedure note indicated "successful CT-guided core biopsy of left upper lung zone mass" and stated that "the specimen was deemed to be adequate."

15. Respondent's final evaluation included smears used for adequacy assessment and slides from a cell block that had a single, minute, less-than-1-mm piece of tissue. On or about October 12, 2012, Respondent issued a report diagnosing "lymphoid tissue with crushing artifact" and noted that there were "no pulmonary epithelium identified." Respondent did not order any deeper levels or special stains.

16. Respondent discussed the case with an Investigator and Medical Consultant for the Health Quality Enforcement Unit at interviews conducted over the course of three days in 2016. She stated that by the time she contacted patient J.H.'s physician, the patient was already scheduled for re-biopsy. She stated she believed the specimen was lymphoid tissue and that special stains were unlikely to be helpful because it would be impossible to take a diagnostic work-up of any lymphoid process to where it would need to go, with the tiny specimen (not enough to do all the needed stains, no tissue for flow cytometry, and poor cellular detail to assess).

17. On or about the morning of October 12, 2012, patient J.H. underwent a bronchoscopy with brushings and biopsy. Immunostains were performed. On or about October 17, 2012, the pathologist who was the director of the lab at KMC issued a report diagnosing small cell carcinoma.

18. On or about October 24, 2012, after Respondent and the pathologist who was the director of the lab at KMC reviewed the case of Respondent's October 12, 2012, report of the biopsy from October 9, 2012, a modified report was issued. The modified report diagnosed "small blue round cells with crushing artifact." It included a new comment: "tissue in the cell block is small therefore it is not sent for immunohistochemical study."

19. In or around September of 2013, the pathologist who was the director of the lab at KMC again reviewed the case of Respondent's October 12, 2012, report of the biopsy from

[4] The smears were designated Code 2, meaning cells present but not specifically diagnostic.

October 9, 2012. Immunostains were performed. A synaptophysin immunostain was positive, supporting a diagnosis of neuroendocrine tumor such as small cell carcinoma. A lymphoid stain was negative, refuting Respondent's initial diagnosis of "crushed lymphoid cells."

20. Taken individually or collectively, Respondent committed gross negligence in her pathology review from the CT-guided biopsy patient J.H. underwent on October 9, 2012, when she:

(a) Failed to instantly recognize abnormal cells;

(b) Failed to recognize that immunostains needed to confirm the main entity in the differential diagnosis generally work well on suboptimal material;

(c) Failed to perform a thorough work-up including ordering immunostains needed to confirm the main entity in the differential diagnosis; and

(d) Failed to have a timely, productive and informed conversation with the surgeon about how further work-up of the material may produce sufficient results, possibly eliminating the need for a repeat biopsy.

Patient G.S.

21. On or about June 18, 2013, patient G.S., 62 year old female, underwent a gastric biopsy which was completed at 11:13 a.m. The patient's gastroenterologist requested a pathology examination and submitted tissue from the procedure to the KMC lab, received there at 1:00 p.m. The one-page pathology request form is a pre-printed form mostly completed by hand. However, in the far upper right hand corner, it contains typed patient identifying information and a bar code, presumably affixed there with a label. Below that, also presumably affixed there with a label, it contains the patient's name, medical record number and information about the specimen, including its assigned accession number, the date the specimen was taken and the type of specimen. Here, the typed accession number was "SP 13 3107," the date the specimen was taken was June 18, 2013, and the type of specimen was "Antral." The handwritten information and boxes checked indicated that: a histology of tissue was requested; the pre-operative diagnosis was anemia; the procedure was "EGD"; the post-operative diagnosis was gastritis; the specimen was in formalin; 6 bites were taken and the specimen type/originating site was "antral." No box

was checked indicating the priority as "routine" or "rushed."

22. Three days later, on or about June 21, 2013, at 9:55 a.m., Respondent electronically signed her pathology report regarding patient G.S. and specimen SP 13 3107. Respondent had dictated her gross examination which was typed by "mh." The gross examination stated: "Received in formalin, labeled with the patient name and 'antrum.' Specimen consists of multiple pieces of tan-brown tissue, measuring 0.6 x 0.4 . 0.2 cm in toto. Specimen is filtered and submitted in one cassette. Giemsa stain ordered." Respondent also dictated her diagnosis which was also typed by "mh." The diagnosis stated: "Stomach, Antrum, Biopsy: Mild Chronic Gastritis; Giesma stain negative for helicobacter pylori; No intestinal metaplasia or malignancy."

23. As described below, another patient, A.C., had undergone the same type of procedure by the same doctor, on the same day, June 18, 2013, just after patient G.S. The pathology request forms and specimens were received at the KMC lab within minutes of each other. The pathology request forms including the specimen descriptions were nearly identical. Patient A.C.'s accession number was one digit different, "SP 13 3108." The gross examinations in both cases were identical. The first version of the pathology reports also contained identical diagnoses.

24. Reportedly such cases are received and "set up" by lab staff -- accessioned, given case number, cassette(s) with case numbers placed on specimen container(s) for pathologist use. Images of the cassette from this case (3107) and the case of patient A.C. (3108) show the labeling process to have started with machine labeling - which Respondent states she did not know how to do and so that was done by a histotech.

25. Sometime after both reports were released and received by the referring gastroenterologist, he reportedly phoned the KMC pathology department stating the diagnoses did not correlate with his impressions - that the patient who had a gastric mass (G.S.) was given a benign diagnosis while the patient who did not have a mass (A.C.) was given a diagnosis of adenocarcinoma.

26. At this point Respondent investigated and ultimately decided to reassign the slides and the blocks on cases 3107 and 3108—switching the specimen identification information between G.S. and A.C.— without discussing the situation with the lab director, risk management

or the referring gastroenterologist.

27. Respondent committed gross negligence in managing the error that she discovered with the pathology cases of patients G.S. and A.C. when she failed to immediately bring the issue to the attention of the lab's medical director and risk management.

Patient B.R.

28. On or about June 11, 2013, patient B.R., a 60-year-old female, underwent a right thoracentesis for pleural effusion. Chemistry results stated a specimen time of 4:30 p.m. A pleural fluid sample was provided to the KMC pathology lab. Reportedly, in the clinical lab, Respondent reviewed a smear with abnormal findings so she requested cytology.

29. On or about June 14, 2013, at 9:03 a.m., the KMC pathology lab received the cytology part of the specimen from patient B.R.'s procedure on June 11, 2013.

30. On or about June 14, 2013, patient B.R. received a second (therapeutic, this time) thoracentesis. At the time, cytology from the June 11, 2013, procedure was still pending.

31. On or about June 18, 2013, patient B.R. underwent bronchoscopy with more pathology specimens. (Reportedly, those lung path specimens were read out as benign.) At the time of the bronchoscopy on June 18, 2013, cytology from the June 11, 2013, procedure was still pending.

32. On or about June 21, 2013, patient B.R. underwent a third thoracoscopy. At the time the decision was made to perform the procedure, cytology from the June 11, 2013, procedure was still pending.

33. On or about June 21, 2013, at 6:28 p.m., Respondent's frozen section of the follow-up June 21, 2013, pleural biopsy showed adenocarcinoma in the specimen.

34. On or about June 21, 2013, at 10:28 p.m., Respondent signed out of the cytology report of the specimen from June 11, 2013. The report stated: "The cell block was made from the remaining specimen sent to clinical lab. Was requested by Dr. Chen after reviewing the smears." The cell block had been sent to an outside lab for immunostains that did not include the TTF-1 stain for lung adenocarcinoma. Subsequent to obtaining the June 11, 2013 specimen, the TTF-1 stain for lung adenocarcinoma had been ordered on the follow up biopsy where the clinical

question about origin of the malignancy was unchanged from what it had been at the time of the cytology case.

35. The report made no reference to any preliminary conversations with any other doctor about highly abnormal cells being present or what was in progress.

36. Previously, an immunostain for calretinin (a mesothelial marker) was negative and an immunostain for keratins showed strong positive CK7. Therefore, it was unnecessary for the work up on the June 21, 2013, biopsy to target mesothelial origin or renal cell carcinoma, yet stains doing that were ordered.

37. On or about August 13, 2013, Respondent agreed with the pathologist who was the director of the lab at KMC that the TT-1 stain was positive and she issued a modified report. In the modified report, the diagnosis was unchanged but the IHC interpretation was changed to TTF-1 being positive and that "the results support pulmonary primary and exclude mesothelioma and metastatic renal cell carcinoma."

38. Taken individually or collectively, Respondent committed gross negligence when she:

(a) Failed to correctly interpret or record TTF-1 stain in her report;

(b) Failed to state her finding of an adenocarcinoma of lung origin in her modified report.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

39. Respondent is subject to disciplinary action under section 2234, subdivision (c), in that she was repeatedly negligent in handling the pathology cases of eight patients. The circumstances are as follows:

Patient J.D.

33. The facts and circumstances as alleged in paragraphs 9 through 11 are incorporated here as if fully set forth.

40. Taken individually or collectively, Respondent committed negligence when she:

(a) Failed to recognize malignancy of any type before ordering stains;

(b) Failed to diagnose or classify the malignancy;

(c) Failed to order a multi-stain panel; and

(d) Misinterpreted the calretinin stain as being positive for calretinin.

Patient J.H.

33. The facts and circumstances as alleged in paragraphs 13 through 19 are incorporated here as if fully set forth.

41. Taken individually or collectively, Respondent committed negligence in her pathology review from the CT-guided biopsy patient J.H. underwent on October 9, 2012, when she:

(a) Failed to instantly recognize abnormal cells;

(b) Failed to recognize that immunostains needed to confirm the main entity in the differential diagnosis generally work well on suboptimal material;

(c) Failed to perform a thorough work-up including ordering immunostains needed to confirm the main entity in the differential diagnosis; and

(d) Failed to have a timely, productive and informed conversation with the surgeon about how further work-up of the material may produce sufficient results, possibly eliminating the need for a repeat biopsy.

Patient G.S.

33. The facts and circumstances as alleged in paragraphs 21 through 26 are incorporated here as if fully set forth.

42. Respondent was negligent in managing the error that she discovered with the pathology cases of patients G.S. and A.C. when she failed to immediately bring the issue to the attention of the lab's medical director and risk management.

Patient B.R.

33. The facts and circumstances as alleged in paragraphs 28 through 37 are incorporated here as if fully set forth.

43. Taken individually or collectively, Respondent committed negligence when she:

(a) Failed to correctly interpret or record TTF-1 stain in her report;

(b) Failed to state her finding of an adenocarcinoma of lung origin in her modified report.

(c) Failed to quickly diagnose without stains or at least after simple in-house mucin stain (not ordered), the presence of malignancy;

(d) Failed to order TTF-1 immunostain to facilitate identification as a lung primary; and

(e) Failed, in the modified report dated August 13, 2013, to clearly state and explain important diagnostic changes and alert the reader to exactly what had changed as compared to the initial report.

Patient L.E.

44. On or about January 28, 2013, patient L.E., a 22 year old female, underwent a trans-sphenoidal resection of a pituitary mass. Respondent interpreted an intraoperative frozen section as "no malignancy." The following day, Respondent analyzed the initially frozen tissue and some additional tissue from the same surgical site. Respondent's report listed a diagnosis of pituitary adenoma and noted: "The sections show fragments of pituitary adenoma with psammoma body and small portion of bone."

45. Subsequently, patient L.E.'s surgeon contacted Respondent and asked her to do stains to evaluate for Coccidioidomycosis due to a past history of same. Respondent ordered PAS and GMS stains and, on or about February 20, 2013, issued a modified report adding: "Per clinician's request, patient is s/p Coccidioidomycosis. Therefore PAS and GMS stains are performed. They stain positive for spherules with endospores consistent with Coccidioidomycosis." Even though Respondent's interpretation was exceptionally unlikely, there is no indication that she showed the case to a colleague before issuing the modified report.

46. Although there may have been compelling reasons Respondent should not have agreed to order the stains requested, Respondent failed to consult the clinical physician to provide any consultation or test utilization guidance. Specifically, Respondent failed to ask the surgeon relevant clarifying questions. Certain answers would have meant that the pre-test probability of Coccidioidomycosis in the location –without even seeing the tissue microscopically –was

exceedingly low. Additionally, properly considering the microscopic findings with the tissue milieu being pituitary adenoma, the pre-test probability fell to essentially zero for a diagnosis of Coccidioidomycosis. The complete lack of inflammation or granulomas, that the structures had typical H and E stain features of psammoma bodies, that they were scattered right in the middle of a typical pituitary adenoma and that psammoma bodies are in fact common in certain types of pituitary adenomas, including prolactinomas, and L.E.'s pre-op history noted "galactorrhea," which is associated with prolactin production.

47. Subsequently, during intradepartmental retrospective review, the PAS/GMS stains that Respondent had found to be positive for spherules and consistent with Coccidioidomycosis were instead found to be spherules probably due to artifact and the specimen was properly found to be negative for Coccidioidomycosis.

48. Taken individually or collectively, Respondent committed negligence when she:

(a) Failed to maintain control over the patient's pathology case and provide appropriate consultation and test utilization guidance to clinical physicians;

(b) Failed to correctly interpret fungal stains;

(c) Failed to appreciate the very limited likelihood of Coccidioidomycosis in the specific tissue sample;

(d) Failed to show the case to a colleague before signing out the case, particularly since the interpretation being contemplated would be exceptionally unlikely.

Patient M.H.

49. On or about April 24, 2013, patient M.H., a 74-year-old female with left inguinal lymphadenopathy had an excisional biopsy of a node. Flow cytometry was not diagnostic. No diagnosis was made at KMC and the case was quickly referred to UCLA Pathology.

50. On or about May 6, 2013, Respondent issued a report noting the case was being sent to UCLA.

51. After not receiving any report or communication from UCLA for an extended period, Respondent called UCLA and spoke to an unnamed pathologist. A verbal preliminary diagnosis to the effect of T-cell lymphoma, with subclassification is pending, was reportedly communicated

to Respondent by the UCLA pathologist. Following that phone conversation, on or about May 16, 2013, Respondent issued a modified report stating that the "preliminary diagnosis from UCLA" was "T-cell lymphoma, subclassification pending IHC and other studies."

52. On or about June 11, 2013, UCLA issued a final diagnosis that was significantly different, for Nodular Lymphocyte Predominant Hodgkin lymphoma.[5] It was faxed to Respondent's attention at KMC on or about June 11, 2013 at 9:30 p.m. hours. After September 24, 2013, Respondent no longer worked at KMC. On or about December 10, 2013, the other pathologist at KMC issued a second modified report with final UCLA diagnosis.

53. When interviewed by a Health Quality Enforcement Unit investigator and medical consultant over the course of three interviews in 2016, Respondent indicated that she had no recollection of having seen the final UCLA report or of having received any further phone communication from that department.

54. Respondent was negligent when she failed to exercise shared responsibility for following up on the send-out case to ensure full, accurate and timely final diagnosis.

Patient M.B.

55. On or about July 23, 2013, patient M.B., a 62 year old male, with a right frontal lobe ring-enhancing lesion underwent craniotomy. Respondent provided an intra-operative pathology consultation on a specimen of the frontal lesion. On the consultation form, for the intra-operative diagnosis, she wrote "spherules with endospores noted -await permanents" and that she had called the attending surgeon.

56. On or about July 26, 2013, Respondent issued her surgical pathology report based on her evaluation of permanent sections of the frozen section tissue along with additional non-frozen tissue. The final diagnosis was "consistent with AV malformation" (arteriovenous malformation - AVM) and it referenced a note. The note stated, "The sections show fragments of brain parenchyma with hemorrhage, focal infarction and thickened wall vessels with granulation tissue." Additionally, it commented to the effect that while "spherules" were seen at frozen

[5] This type of lymphoma is significantly more indolent than most forms of T-cell lymphoma.

section, later PAS and GMS stains do not show microorganisms.

57. When discussing the case with an Investigator and Medical Consultant for the Health Quality Enforcement Unit at interviews conducted over the course of three days in 2016, Respondent indicated that she advised the surgeon to submit tissue for a culture. Infection was a differential diagnosis. In the course of evaluating her pathology case, Respondent did not look up the micro-results for the brain biopsy although infection was a differential diagnosis, she had requested the surgeon to submit tissue and the specimen was necrotic and inflamed tissue, so abscess or encephalitis from other organisms should have been a consideration.

58. Subsequently, given that the nature of the tissue necrosis and inflammation were unclear and that Respondent had found the case to be consistent with AVM, the case was sent to another facility for analysis. The analysis came back different and on or about August 9, 2013, Respondent issued a modified pathology report adopting the modified findings which were: "Reactive lymphohistiocytic lesion with hemorrhagic necrosis and cavitation. Negative for vasculitis, lymphoma, neoplasm, vascular malformation, granuloma and select microorganisms."

59. Taken individually or collectively, Respondent committed negligence when she:

(a) Advised the surgeon during the intraoperative consultation that she noted "spherules with endospores" which is understood by doctors in the area to mean it is virtually certain that Coccidioides organisms are present;

(a) Failed to look up micro lab results in a brain biopsy that had infection in its differential diagnosis after having advised the surgeon to submit such a sample to micro lab; and

(c) Found the patient's diagnosis to be "consistent with AVM."

Patient A.C.

60. On or about June 18, 2013, patient A.C., a 62-year old male underwent a gastric biopsy. The procedure was performed by the same doctor who, earlier that day, had performed the same procedure on patient G.S., referenced above. The pathology request form's labels in the upper right hand corner include the patient's identifying information and the typed accession number "SP 13 3108." Handwritten information and boxes checked indicated that: a histology of tissue was requested; the pre-operative diagnosis was abdominal pain; the procedure was "EGD";

the post-operative diagnosis was severe gastritis; the specimen was in formalin; 6 bites were taken and the specimen type/originating site was "antrum." The priority was marked "routine."

61. On or about June 19, 2013 at 11:49, Respondent electronically signed her pathology report regarding patient A.C. and specimen SP 13 1308 electronically. Respondent had dictated her gross examination which was typed by "mh/mav." The gross examination stated: "Received in formalin, labeled with the patient name and 'antrum.' Specimen consists of multiple pieces of tan-brown tissue, measuring 0.6 x 0.4 . 0.2 cm in toto. Specimen is filtered and submitted in one cassette. Giemsa stain ordered." Respondent had dictated her diagnosis which was typed by "mav." The diagnosis stated: "Stomach, Antrum, Biopsy: Mild Chronic Gastritis; Giesma stain negative for helicobacter pylori; No intestinal metaplasia or malignancy."

62. On June 21, 2013, Respondent realized the case had been signed out prematurely. Reportedly this was due to unintended insertion of a commonly used benign "gastritis" template. She had recognized that the slide showed adenocarcinoma and she had meant to hold the case to investigate it further.[6] When she discovered the diagnosis had been mistakenly released, on June 21, 2013 at 3:54 p.m., she issued the first modified report. It stated: "Pending prior pathology report and slides and consultation," mentioning the prior pancreas surgery and that the case was discussed with the gastroenterologist.[7]

63. On or about June 28, 2013, Respondent released a second modified report which stated, "Invasive adenocarcinoma moderately differentiated." Sometime after June 28, 2013, as referenced above, the referring gastroenterologist received the reports on both this case (malignant) and case 3107 (benign). He reportedly phoned the KMC pathology department stating the two diagnoses did not correlate with his impressions - that the patient who had a gastric mass (G.S.; 3107) received a benign diagnosis while the patient who did not have a mass

[6] She had reviewed A.C.'s medical record and seen that he had a history of prior benign pancreatectomy which raised a question for her whether the gastric carcinoma might be from the pancreas if a malignant diagnosis there had been missed.

[7] There is nothing in the testimony that the gastroenterologist communicated to Respondent at that time that a cancer diagnosis seemed not to correlate with this patient's EGD findings - that would come later.

(A.C.; 3108) received diagnosis of adenocarcinoma

64. Respondent was negligent with regard to patient A.C. when she prematurely released the pathology report with the incorrect diagnosis (as compared to what was on the slides at the that time).

THIRD CAUSE FOR DISCIPLINE

(*Incompetence*)

65. Respondent is subject to disciplinary action under section 2234, subdivision (d), of the Code in that she was incompetent in the care and treatment of two patients. The circumstances are as follows:

66. The facts and circumstances alleged in paragraphs 55 through 58 are incorporated here as if fully set forth.

67. Respondent demonstrated in the case of M.B. that she lacks knowledge with respect to diagnosis of arteriovenous malformation of brain.

FOURTH CAUSE FOR DISCIPLINE

(General Unprofessional Conduct)

68. Respondent is subject to disciplinary action under section 2234 of the Code in that he committed general unprofessional conduct. The circumstances are as follows:

69. The facts and circumstances alleged in paragraphs 8 through 67 are incorporated here as if fully set forth.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate Number 51848, issued to Beiru Jia Chen, M.D.;

2. Revoking, suspending or denying approval of Beiru Jia Chen, M.D.'s authority to supervise physician assistants, pursuant to section 3527 of the Code;

3. Ordering Beiru Jia Chen, M.D., if placed on probation, to pay the Board the costs of probation monitoring; and

4. Taking such other and further action as deemed necessary and proper.

DATED: October 7, 2016

KIMBERLY KIRCHMEYER
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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